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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:
Patrick D. MIZE

SERIAL NO: 10/721,498 GROUP: 1654

FILED: November 26, 2003 EXAMINER: Louise N. LEARY

FOR: LOW MOLECULAR WEIGHT HEPARIN ASSAY AND REAGENTS THEREFOR

LETTER

Mail Stop DD
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is a R.O.C (Taiwan) Office Action for the Examiner's consideration. The reference(s) cited therein have been previously filed on November 26, 2003 and May 25, 2005.

Respectfully Submitted,

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PRELIMINARY NOTICE OF REJECTION OF THE IPO
(TRANSLATION)

Issuance Date: 10 January 2006

1. Applicant: CARDIOVASCULAR DIAGNOSTICS, INC.

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SUBJECT:

After examination, the IPO considers that the subject ROC (Taiwan) Patent Application No. 091135438 has the indefinite points as indicated in the following EXPLANATION (3). The applicant is required to file a response in duplicate by **9 March 2006** if any substantive counter-evidence or arguments are present. If the applicant fails to act according to the notice within the time limit, the IPO shall proceed with the examination on the basis of the materials on hand.

EXPLANATION:

(1) If the applicant wishes to make supplements/amendments, the applicant should act according to the provisions of the Patent Law, Articles 48 and 49, and the Enforcement Rules of the Patent Law, Article 28.

(2) If the applicant wishes to appear before the IPO for a face-to-face demonstration or explanation, please explicitly indicate "Interview Requested" in the response and effect the payment of a government fee of NT$1,000. The place and time for conducting an interview will be arranged if the IPO considers it necessary to conduct an interview.

(3) Upon examination, it is considered:

   (a) The subject application, entitled "LOW MOLECULAR WEIGHT HEPARIN ASSAY, SYSTEM AND REAGENT THEREFOR," is examined based on the specification submitted by the applicant on 6 December 2002. The priority date of the subject application is 7 December 2001. The subject application includes 26 claims, among which Claims 1, 13, 14, 17, 23 and 26 are independent claims and the rest are dependent claims.

   (b) Claim 1 is directed to a method for measuring low molecular weight heparin concentration on a whole blood sample, comprising steps (i) and (ii). Upon examination, it is found that WO 01/44493 (Citation 1,

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published on 21 June 2001) discloses an assay for measuring low molecular weight heparin concentration on a sample based on the relationship between coagulation time and low molecular weight heparin amount in the sample. Citation 1 also discloses that factor Xa or factor Xa activator has a function in accelerating coagulation and that factor Xa activator comprises snake venom such as RVV-V.

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WO 99/10746 (Citation 2, published on 4 March 1999) also discloses a method for determining the concentration of low molecular weight heparin in a blood sample based on measuring the time to clot formation (see pages 3 to 5 of the specification and Claim 1).

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WO 89/10788 (Citation 3, published on 16 November 1989) discloses a method and apparatus for the measurement of clot formation time in a whole blood sample (see Claims 4, 5 and 7) and its application in the determination of heparin.

Although Citations 1 and 2 do not disclose the use of magnetic particles and dry assay reagents in measuring low molecular weight heparin concentration, the application of magnetic particles and dry assay reagents has been disclosed in Citation 3. Therefore, the method for measuring low molecular weight heparin concentration on a whole blood sample of the subject invention can be easily accomplished by persons skilled in the art in view of the prior art known prior to the filing of the subject application. The subject invention does not have an inventive step and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

Claims 2 to 12 directly or indirectly depend from Claim 1 and are to further limit the scope of Claim 1. For the same reasons as stated above, these claims do not have an inventive step and do not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(c) Claim 13 is directed to a method for measuring low molecular weight heparin concentration on a whole blood sample, comprising steps (i) and (ii). The drawings and Claims 12 to 14 and 19 of Citation 3 have disclosed the application of the method of Claim 13 of the subject application in a whole blood sample. Citations 1 and 2 also disclose an assay for measuring low molecular weight heparin concentration on a sample based on the relationship between coagulation time and low molecular weight heparin amount in the sample, and the use of snake venom such as RVV-V as factor Xa activator. Therefore, Claim 13 can be easily accomplished by persons skilled in the art in view of the prior art known prior to the filing of the subject application, does not have an

inventive step, and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(d) Claim 14 is directed to a kit for measuring low molecular weight heparin concentration on a whole blood sample, comprising, in one or more containers, a permanent magnet, a timing means, and an element containing at least one dry coagulation assay reagent and magnetic particles, wherein the dry coagulation assay reagent comprises a Factor Xa activator. As stated above, this claims does not have an inventive step and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

Claims 15 and 16 directly or indirectly depend from Claim 14 and are to further limit the scope of Claim 14. For the same reasons as stated above, these two claims do not have an inventive step and do not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(e) Claim 17 is directed to a system for measuring low molecular weight heparin concentration on a whole blood sample, comprising (i) an instrument as defined therein and (ii) an element as defined therein. Citations 1 and 2 have disclosed an assay for measuring low molecular weight heparin concentration on a sample based on the relationship between coagulation time and low molecular weight heparin amount in the sample, and the use of snake venom such as RVV-V as factor Xa activator. Therefore, the system of Claim 17 and the instrument and element comprised in the system have been disclosed in the citations and can be easily accomplished by persons skilled in the art in view of the prior art known prior to the filing of the subject application. This claim does not have an inventive step and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

Claims 18 to 22 directly or indirectly depend from Claim 17 and are to further limit the scope of Claim 17. As stated above, these claims do not have an inventive step and do not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(f) Claim 23 is directed to a system for measuring low molecular weight heparin concentration in a whole blood sample, comprising (i) a reaction element as set forth therein, (ii) a sample well and a reaction chamber being in fluid communication through a transport zone of geometry, (iii) means for optically monitoring said reaction chamber, (iv) means for subjecting said reaction chamber to an oscillating magnetic field, and (v) providing a measurement of the kinetics of said coagulation assay. Citation 3 has disclosed the apparatus and its application. Citations 1 and 2 have

disclosed an assay for measuring low molecular weight heparin concentration on a sample based on the relationship between coagulation time and low molecular weight heparin amount in the sample, and the use of snake venom such as RVV-V as a Factor Xa activator. Therefore, this claim can be easily accomplished by persons skilled in the art in view of the prior art known prior to the filing of the subject application, does not have an inventive step, and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

Claims 24 and 25 directly or indirectly depend from Claim 23 and are to further limit the scope of Claim 23. As stated above, these claims do not have an inventive step and do not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(g) Claim 26 is directed to a method for measuring low molecular weight heparin concentration in a whole blood sample, comprising steps (i) to (iii). As stated above, this claim can be easily accomplished by persons skilled in the art in view of the prior art known prior to the filing of the subject application, does not have an inventive step, and does not meet the provisions of the Patent Law, Article 22, Paragraph 4.

(4) If the applicant makes supplements/amendments to the specification or drawings, a written application for such supplements or amendments in duplicate, a marked-up version of the amended specification or drawing pages in duplicate, and a clean, replacement version of the amended specification or drawing pages in triplicate shall be submitted. If the supplements/amendments render the page numbers of the original specification or drawings out of succession, the whole specification or drawings with the supplements/amendments in triplicate shall be submitted.